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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/876,132	06/23/1997	TIMOTHY FOWLER	CG372	4697

7590

01/05/2005

GENENCOR INTERNATIONAL, INC.  
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EXAMINER
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SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 08/876,132	<b>Applicant(s)</b> FOWLER ET AL.	
	<b>Examiner</b> Daniel M Sullivan	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-24,26,29,31-36 and 39-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29,31 and 32 is/are allowed.
- 6) ☒ Claim(s) 21-24,33-35 and 39-43 is/are rejected.
- 7) ☒ Claim(s) 26,36 and 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/1/04</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

This Office Action is a reply to the Paper filed 14 October 2004 in response to the Non-Final Office Action mailed 22 March 2004. Claims 21-38 were considered in the 22 March Office Action. Claims 25, 27, 28, 30, 37 and 38 were canceled, claims 21, 26, 29 and 33-36 were amended and claims 40-44 were added in the 14 October Paper. Claims 21-24, 26, 29, 31-36 and 39-44 are presently pending and under consideration.

***Information Disclosure Statement***

The information disclosure statement filed 1 June 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Specifically, the Ausubel *et al.* and Sonoyama *et al.* references have not been considered because no legible copy has been provided. The references have therefore been lined through on the considered PTO-1449. The other references lined through on the form were previously made of record in the IDS filed 27 August 1998.

***Response to Amendment and Arguments***

Objection to and rejection of claims 25, 27, 28, 30, 37 and 38 is rendered moot by cancellation of the claims.

Art Unit: 1636

Claim Rejections - 35 USC § 112

Rejection of claims 21-24, 29 and 31-36 under 35 U.S.C. 112, first paragraph, as comprising new matter is withdrawn in view of the amendments to the claims such that the percent identity is recited relative to the sequence set forth in SEQ ID NO: 1 and SEQ ID NO: 2.

Rejection of claims 26, 29, 31, 32 and 36 under U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendments.

Claims 21-24 and 33-35 stand rejected and newly added claims 39-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record.

The base claims 21 and 33 have been amended such that the cryptic plasmid eliminated in the method is now limited to having a nucleic acid sequence of at least 90% sequence identity with SEQ ID NO: 1 and SEQ ID NO: 2, and claim 21 has been amended to recite that the improved strain is able to grow at higher temperatures than the progenitor strain as already recited in claim 33.

As stated in previous Office Actions, the instant disclosure provides a single example of a progenitor strain useful in the instant claimed method, which is not representative of the genus of any *Enterobacteriaceae Pantoea*, *Enterobacter*, *Erwinia* or *Gluconobacter* strain comprising a plasmid which alters the growth or mobilization characteristics such that when the plasmid is eliminated the growth characteristics are

Art Unit: 1636

improved or the mobilization properties are reduced, and the specification fails to teach the relevant identifying characteristics of the strain of the claims. Although the progenitor strain is now limited to comprising a plasmid having 90% identity with SEQ ID NO: 1 and SEQ ID NO: 2, there is no evidence of record that the limitations recited in the claim correlate with a progenitor strain that can be used in the method. As discussed in the previous Office Action, the specification sets forth no structural limitations which are correlated with the functional limitations aside from the pS plasmid comprising both SEQ ID NO: 1 and SEQ ID NO: 2. Although the skilled artisan might expect that a genus limited to comprising a plasmid having 95% sequence identity with SEQ ID NO: 1 and SEQ ID NO: 2 would be comprised of predominantly strains having the recited function, given the absence of a disclosed structure-function relationship, the skilled artisan would not have viewed the application as providing adequate descriptive support for a genus wherein the plasmid has less than 95% identity with SEQ ID NO: 1 and SEQ ID NO: 2. The additional limitations recited in claims 22-24, 34, 35, 39 and 40 do not cure the deficiencies of claim 21. It is noted that although claim 40 recites, “the cryptic plasmid has a nucleic acid sequence of SEQ ID NO: 1 and SEQ ID NO: 2” (emphasis added), the claim only requires that the nucleic acid comprise a fragment of the sequences set forth as SEQ ID NO: 1 and SEQ ID NO: 2 because the limitation only requires that the nucleic acid comprise a sequence, any sequence, of SEQ ID NO: 1 and SEQ ID NO: 2. The claim would be allowable if amended to use the definite article “the” instead of the indefinite article “a” in referring to the sequence.

Newly added claim 41 is directed to a method for obtaining an improved *Pantoea* strain comprising eliminating a cryptic plasmid having a nucleic acid sequence which

Art Unit: 1636

encodes the polypeptide having the sequence of SEQ ID NO: 3. However, upon consideration of the record as a whole, the skilled artisan would not expect that the presence of a nucleic acid encoding the sequence of SEQ ID NO: 3 to adequately describe a genus of all *Pantoea* progenitor strains that can be used in the method. The specification does not set forth the functional characteristics of the nucleic acid encoding SEQ ID NO: 3 or a polypeptide comprising SEQ ID NO: 3 such that the skilled artisan would expect that the presence of a nucleic acid encoding SEQ ID NO: 3 would identify all *Pantoea* progenitor strains useful in the method. For reasons of record, the skilled artisan does not know which elements present in the cryptic plasmid comprising SEQ ID NO: 1 and SEQ ID NO: 2 are required for the function recited in the claims, including whether the nucleic acid encoding SEQ ID NO: 3 is sufficient for the recited function. Therefore, the skilled artisan would not have viewed the specification as adequately demonstrating possession of the full scope of the subject matter of claims 41-43.

Rejection of claims 26, 29, 31, 32 and 36 under U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the amendment thereto.

Claims 21-24 and 33-35 stand rejected and newly added claims 39-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for preparing an improved *Enterobacteriaceae* strain from a progenitor *Enterobacteriaceae* strain, wherein said progenitor *Enterobacteriaceae* strain comprises the cryptic plasmid pS or a plasmid having 95% sequence identity with SEQ ID NO: 1

Art Unit: 1636

and SEQ ID NO: 2, does not reasonably provide enablement for the method wherein the progenitor *Enterobacteriaceae* comprises a cryptic plasmid other than pS or having less than 95% identity with SEQ ID NO: 1 and SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

As discussed in the previous Office Action, the instant specification provides a single example of an *Enterobacteriaceae* strain useful in the claimed method (i.e., *Pantoea citrea* comprising the 3.8 Kb pS plasmid), and teaches that the phenotype obtained upon elimination of the pS plasmid was unexpected. The disclosure is silent with regard to how to obtain other progenitor strains that could be used in the claimed method other than random trial and error experimentation. Although the relative level of skill in the art is high, the skilled artisan would not be able to use the full scope of the claimed method without engaging in undue experimentation to isolate progenitor strains that could be used in the method. Given the unpredictability of phenotype obtained by eliminating any given plasmid from an *Enterobacteriaceae* strain and the absence of guidance in the art and instant disclosure that would enable the skilled artisan to identify strains useful in the claimed method, the skilled artisan would have to engage in blind trial and error experimentation to test each strain of *Enterobacteriaceae* comprising a plasmid having the structural features set forth in the claims to identify those strains useful in the method.

As discussed above, the amendments to the claims and the limitations of the newly added claims do not sufficiently narrow the scope of the claimed subject matter such that the skilled artisan would expect that the structural limitations to adequately

Art Unit: 1636

correlate with the functional limitations of the claims. Therefore, identifying the enabled embodiments within the scope of the rejected claims would still require undue experimentation. Therefore, the claims are properly rejected under 35 USC §112, first paragraph, as lacking a fully enabling disclosure.

### *Allowable Subject Matter*

Claims 26, 36 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 29, 31 and 32 are allowed.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the



Art Unit: 1636

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M. Sullivan, Ph.D.  
Examiner  
Art Unit 1636

  
DAVID GUZO  
PRIMARY EXAMINER